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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,708	04/30/2001	Michael J Evelegh	RDMA-002XX	3616

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EXAMINER	
GUO, LYNDA T	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/830,708	EVELEGH, MICHAEL J	
	Examiner	Art Unit	
	Lynda T Guo	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *15-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 April 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Applicant's response to restriction and amendment (Paper No. 6) received on 04 November 2002 has been entered.

NOTE: In the last Office Action, a mistake was made in restriction claims grouping. The correct groupings is as follows:

Group I, Claim 1 (partial) and claims 2-14 (full), drawn to a process, system and kit for the analysis of biological samples.

Group II, Claim 1 (partial) and claims 15-22 (full), drawn to a process and a kit for determining skin cholesterol levels.

The corrected claim groupings do not affect Applicant's election of Group I. As such, Claims 1-14 are examined in this Office Action.

Election/Restrictions

1. Applicant's election with traverse of inventive Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that "examination of all of the claims is not seen as imposing an undue burden on the Examiner". This is not found persuasive because the two Groups are drawn to divergent subject matter (e.g. Group I is drawn to an *in vitro* analytical system whereas Group II is drawn to an *in vivo* analytical system), which qualifies each to be classified differently. The difference in classification would require different and separately burdensome bibliographic and computer searches. Additionally, the two inventive Groups also do not relate to a single general inventive concept, the reasons for which are recited in the previous Office Action.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Canada on 06 August 1999 for application CA 2279793, on 17 January 2000 for application CA 2296163 and on 20 April 2000 for application CA 2306315. It is noted, however, that applicant has **not** filed a certified copy of the above three applications as required by 35 U.S.C. 119(b).

Specification

4. The disclosure is objected to because of the following informalities: some grammatical errors were found (see following).

On page 10, line 16, an end quotation mark (") is missing after the word, Spectrophotometer.

On page 12, line 6, "Such **as** glass fiber material..." is awkward. Examine suggests replacing the "as" with "a".

Appropriate correction is required.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "10" has been used to designate both a test strip and a foam pad (see page 19,

lines 18-19 of the present Specification). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "12" and "14", in reference to Figure 1 (see page 19, lines 19-20 of the present Specification) and "26" in reference to Figures 2-4 (see page 20, line 25). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4-6 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "generally white" in claims 4-6 and 13, "substantially pure" in claim 10 and "predominantly" in claim 11 are relative terms which render the claims indefinite. The aforementioned terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In Claim 12, it is unclear what is meant by "system". The term could mean a device, a mechanism or a process.

In Claim 12, "the sample" in lines 5, 9, 15 and 17 lacks proper antecedent basis because in line 2, "samples" is recited.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 1 is drawn to a process of analyzing a biological material in a biochemical or immunological assay for an analyte, comprising the steps of depositing the sample on a substrate, developing color by treating with a reagent and then measuring the color characteristic to determine the presence of absence of an analyte. Claim 2 further specifies the biological material as comprising a liquid or semi-solid body secretion and the analyte is a cancer marker. Claims 3 and 4 further limits the biological material to lung mucus, throat mucus, cervical mucus, colorectal mucus or seminal fluid and color is developed by enzyme reaction or Schiff's reaction on a generally white substrate. Claim 5 limits the biological specimen to colon-contacting semi-solid samples, the analyte is a carbohydrate marker and the specimen is treated with galactose oxidase and then developed with Schiff's reagent. Claim 7 further limits Claim 1 by defining the color characteristic to be hue angle or chroma, which are determined

spectrophotometrically. Claim 8 further limits the substrate of Claim 1 to a non-cellulosic material.

9. Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (WO 90/00251).

Claim 1 is drawn to a process of analyzing a biological material in a biochemical or immunological assay for an analyte, comprising the steps of depositing the sample on a substrate, developing color by treating with a reagent and then measuring the color characteristic to determine the presence of absence of an analyte. Claim 7 further limits Claim 1 by defining the color characteristic to be hue angle or chroma, which are determined spectrophotometrically. Claim 8 further limits the substrate of Claim 1 to a non-cellulosic material.

In WO 90/00251, Lee discloses an apparatus comprising a reflectance spectrophotometer and an immunoassay making use of said apparatus, in which an analyte in the sample is determined by measuring the chromacity and hue of the developed color. They analyte consists of carbohydrate markers on Chlamydia and as reagents an enzyme-labeled antibody and a substrate/chromogen combination are used. The sample is applied to a porous substrate, for example nylon (See page 7, line 20; page 14, last paragraph to page 15, third paragraph and page 16, last paragraph to page 17 end of second paragraph).

The said Claims are thus rejected because all of the limitations are fully encompassed by Lee's disclosure.

10. Claims 1-6, 8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Shamsuddin et al. (USPN 4,857,457) and Shamsuddin (USPN 5,162,202).

The limitations of Claims 1 and 8 are recited above. Claims 2-6, 10 and 11 provide the following limitations: biological specimen is a liquid or semi-solid body secretion (e.g. lung mucus, throat mucus, cervical mucus, colorectal mucus or seminal fluid), particularly a colon-contacting semi-solid sample; analyte is a cancer marker, carbohydrate marker or any marker indicative of abnormalities; the substrate is generally white; the color is developed from an enzyme reaction or Schiff's reaction; and the specimen is contacted with galactose oxidase prior to reacting with Schiff's reagent.

Both USPN 4,857,457 and USPN 5,162,202 disclose methods of screening for large intestinal cancer in which the marker is the disaccharide β-D-Gal(1→3)-D-GalNAc, also known as T-antigen, which is a known marker for colon cancer. Shamsuddin disclosed that the marker can be detected immunologically, enzymatically or oxidation-reductively. The disclosure teaches that a sample of rectal mucus is obtained from a patient and then smeared on a piece of water-insoluble membrane filter. The sample is then treated with galactose oxidase and then with Schiff's reagent, whereby color development is measured to determine the presence or absence of disease. (In USPN 4,857,457, see Abstract; Column 1, lines 51-54; Column 2, lines 40-45 and 51-59; Column 3, lines 1-19; Column 6, lines 54-67; and Column 7, lines 1-8. In USPN 5,162,202, see Abstract; Column 2, lines 50-68; Column 3, lines 1-10; and Column 7 lines 1-26.) The disclosure in USPN 4,857,457 fully anticipates the above-recited Claims, which are consequently rejected.

11. Claims 1-6, 8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Shamsuddin (USPN 5,348,860).

The limitations of the Claims 1-6, 8, 10 and 11 are recited above.

USPN 5,348,860 discloses of the same methods for cancer screening as taught in a related patent recited above (USPN 5,162,202), having the same inventive entity. However, USPN 5,348,860 further teaches that the method is useable on other bodily secretions such as secretions of the breast, prostate, uterus, endocervix and vagina or fluids such as semen, mucus, and sputum and bronchial or alveolar secretions. Thus, USPN 5,348,860 fully anticipates the limitations of the said Claims, which are rejected for the same reasons as recited above. (See Abstract; Column 2, lines 28-33; Column 3, lines 21-45; Column 4, lines 1-7 and 58; Column 6, lines 6-14; Column 7, lines 1-10; and Column 9, lines 8-21.)

12. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Krepinsky et al. (USPN 5,416,025).

The limitations of Claims 1-6, 8, 10 and 11 are recited above. Claim 9 limits the substrate to a glass fiber.

In USPN 5,416,025, Krepinsky teaches that a known screening test to detect for colorectal cancer is the galactose oxidase test, which detects for the T-antigen disaccharide in a rectal mucus sample, using galactose oxidase and Schiff's reagent, as disclosed previously by Shamsuddin et al. in USPN 4,857,457. However, Krepinsky also teaches of a different screening method which comprises collecting colorectal mucus from a patient, depositing the sample on a water-insoluble substrate (such as a filter made of glass microfibers), adding Schiff's reagent, wherein the color that develops is scored or measured. (See Abstract; Column 1, lines 10-15; Column 2, lines 49-52; Column 3, lines 66-67; Column 4, lines 1-7; Column 5, lines 18-22, 47-51 and 67-68; Column 6, lines 1-25; and Column 12, lines 27-37.)

The limitations of Claims 1-6 and 8-11 are thus fully anticipated by Krepinsky and the Claims are therefore rejected.

13. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Krepinsky et al. (USPN 6,187,591,B1).

The limitations of Claims 1-11 are summarized above. Claim 12 is drawn to a system for diagnosing for an abnormality in a liquid or semi-solid body secretion in which the sample is reacted with galactose oxidase and Schiff's reagent then reading the color on a spectrophotometer. Claims 13 and 14 are drawn to a kit for analyzing a colon-contacting semi-solid sample for abnormalities comprising a non-cellulosic substrate (particularly, a glass fiber substrate), Schiff's reagent and a spectrophotometer to read the color developed from the reaction.

In USPN 6,187,591,B1, Krepinsky et al. discloses that a variety of tests are well known in the art for colorectal cancer screening. One of these is the galactose oxidase test, which comprises obtaining a colorectal mucus sample and smearing it on a water-insoluble substrate, treating the sample with galactose oxidase, to detect for the T-antigen marker, and then with Schiff's reagent. The resultant color is analyzed to determine the presence or absence of a diseased state. Krepinsky also discloses of a method in which the use of galactose oxidase is bypassed. In this method, a mucus sample is obtained from the rectum of a patient. The sample is then deposited on a water-insoluble substrate, such as a glass microfiber disc, and Schiff's reagent is added. The color that develops is then detected by spectrophotometric determination. Krepinsky further discloses that the properties analyzed can include, *inter alia*, color, spectral properties,

fluorescence, and chromatographic properties. Krepinsky also discloses of a screening kit comprising the substrate and the Schiff's reagent.

Although Krepinsky does not explicitly disclose that a spectrophotometer is included with the kit, it is implied since the method disclosed utilizes a spectrophotometer for reading the results. In regards to Claim 12, the claimed system includes galactose oxidase as a reagent along with a spectrophotometer. Although Krepinsky only disclose the use of a spectrophotometer in the method which bypasses the use of galactose oxidase, it would have been obvious to one of ordinary skill in the art to also use a spectrophotometer in the method that includes galactose oxidase because both methods results in a colored result which is measurable by a spectrophotometer. Additionally, the results obtained by a spectrophotometer would be more definitive because the visual determination of color can be subjective and variable from person to person.

Therefore, all of the limitations as set forth in Claims 1-14 are fully encompassed and anticipated by Krepinsky's disclosure. The Claims are thus rejected.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shamsuddin (USPN 5,162,202).

The limitations of Claim 12 are summarized above.

In USPN 5,162,202, Shamsuddin teaches of two different methods of detecting for cancer by testing rectal mucus samples. One method is the galactose oxidase test recited in the above rejections, which include the use of galactose oxidase and Schiff's reagent. The other method taught by Shamsuddin is an enzymatic assay using biotinylated lectin and avidin. In this method, peanut agglutinin is coated in a well, the mucus is added and allowed to bind. Then avidin-D-alkaline phosphatase is added followed by the addition of p-nitrophenyl phosphate. The results are read in a spectrophotometer at 405nm. (See Abstract; Column 2, lines 28-33; Column 3, lines 21-45; Column 4, lines 1-7 and 58; Column 6, lines 6-14; Column 7, lines 1-10 and 38-64; and Column 9, lines 8-21.

Although Shamsuddin only disclosed the use of a spectrophotometer in reading results from a reaction involving biotin and alkaline phosphatase, but not in the galactose oxidase method. However, one of ordinary skill in the art would have been motivated to also read the results from the galactose oxidase method in a spectrophotometer because both disclosed methods result in a color development and it is well known in the art that color characteristics can be measured in a spectrophotometer. As Applicant has disclosed, "It is known that color may be defined and expressed in terms of hue angle." (Page 10, lines 22-23 of the present Specification.) This suggests that analysis of results that are color dependent can be measured for a variety of characteristics, such as absorbance or hue. One of ordinary skill in the art would also have been motivated to measure results with a spectrophotometer for the added advantage of quantitating the results in addition to the accuracy and definitiveness of readings afforded by the spectrophotometer. The Claim is therefore obviated and rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Tue - Fri and alternate Mondays (8:00am - 4:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lynda T Guo
Patent Examiner
January 2, 2003

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200